DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

September 26, 2014

Medtronic Sofamor Danek USA, Incorporated
Mr. Lee Grant
Distinguished Regulatory Affairs Advisor
1800 Pyramid Place
Memphis, Tennessee 38132

Re: K133577
Trade/Device Name: CLYDESDALE® Spinal System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX
Dated: August 20, 2014
Received: August 21, 2014

Dear Mr. Grant:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Ronald P. Jean -S for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K133577

Device Name
CLYDESDALE® Spinal System

Indications for Use *(Describe)*
The CLYDESDALE® Spinal System is designed to be used with autogenous bone graft to facilitate interbody fusion and is intended for use with supplemental fixation systems cleared for use in the lumbar spine. The CLYDESDALE® Spinal System is used for patients diagnosed with Degenerative Disc Disease (DDD) at one or two contiguous levels from L2 to S1. DDD patients may also have up to Grade I Spondylolisthesis or retrolisthesis at the involved levels. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. Additionally, the CLYDESDALE® Spinal System can be used to provide anterior column support in patients diagnosed with degenerative scoliosis as an adjunct to pedicle screw fixation. These patients should be skeletally mature and have had six months of nonoperative treatment. These implants may be implanted via a minimally invasive lateral approach.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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CLYDESDALE® Spinal System
510(k) Summary – K133577

September 2014

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Memphis, Tennessee 38132
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Contact: **Lee Grant**
Distinguished Regulatory Affairs Advisor

Proposed Proprietary Trade Name: CLYDESDALE® Spinal System

Classification Name(s): Intervertebral Body Fusion Device (per 21CFR Section 888.3080); Product Code: MAX

Description: The CLYDESDALE® Spinal System consists of PEEK cages of various widths and heights, which can be inserted between two lumbar or lumbosacral vertebral bodies to give support and correction during lumbar interbody fusion surgeries. The hollow geometry of the implants allows them to be packed with autogenous bone graft. When used to supplement pedicle screw fixation systems in adult degenerative scoliosis cases, the CLYDESDALE® device is used as a construct anchor and to help restore sagittal and coronal balance.

The purpose of this 510(k) submission is to expand the indications of the CLYDESDALE® Spinal System to allow the device to be used as a supplement to pedicle screw fixation in patients diagnosed with degenerative scoliosis.

Indications for Use: The CLYDESDALE® Spinal System is designed to be used with autogenous bone graft to facilitate interbody fusion and is intended for use with supplemental fixation systems cleared for use in the lumbar spine. The CLYDESDALE® Spinal System is used for patients diagnosed with Degenerative Disc Disease (DDD) at one or two contiguous levels from L2 to S1. DDD patients may also have up to Grade 1 Spondylolisthesis or retrolisthesis at the involved levels. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. Additionally, the CLYDESDALE® Spinal System can be used to provide anterior column support in patients diagnosed with degenerative scoliosis as an adjunct to pedicle screw fixation. These patients should be skeletally mature and have had six months of nonoperative treatment. These implants may be implanted via a minimally invasive lateral approach.

Summary of the Technological Characteristics: The CLYDESDALE® Spinal System implants contained in this application are identical to those previously cleared in earlier 510(k) applications. The CLYDESDALE® Spinal System remains comprised of convex, bullet-nosed interbody devices intended to facilitate a fusion between two vertebral bodies. The fundamental scientific technology of the CLYDESDALE® Spinal System has not been altered for this submission.

Identification of Legally Marketed Devices: The CLYDESDALE® Spinal System is similar in design to the CAPSTONE®) Spinal System which was cleared for the requested indication in K123027 (SE 07/25/13), the primary predicate. The components contained in this application are identical to those cleared in previous CLYDESDALE® Spinal System applications including K132897 (SE 03/13/14) K122591 (SE 09/18/12), K113528 (SE 12/20/11), K112405 (SE 11/21/11), K100175 (SE 06/02/10), and K083026 (SE 12/29/08). No new implants are included in this application.

Discussion of Supporting Retrospective Clinical Data and Non-Clinical Testing: Published retrospective clinical data for the CLYDESDALE® Spinal System as well as devices similar to the subject spinal system were provided in support of this application. Eight articles specifically referenced CLYDESDALE® Spinal System interbody cages as the implants used in adult degenerative scoliosis cases, while another six articles referenced the primary predicate device (CAPSTONE® Spinal System) as the interbody cage used in similar procedures. All of the CLYDESDALE® patients were treated via a minimally invasive lateral approach. Fusion results were not provided in all papers, but improvement in various pain score measurements (Visual Analogue Scale, Oswestry Disability Index, and Treatment Intensity Score) were comparable to those reported in the literature for similar patients treated with CAPSTONE® Spinal System interbody devices used with posterior fixation. Comparable improvements in deformity correction were also reported in patients. No changes were made to the existing devices, nor were any new components added to the system. Therefore, no additional testing was required or performed.

Conclusion: The design features, materials used, manufacturing and sterilization methods are equivalent to the previously cleared CLYDESDALE® Spinal System components with the exception of broadening a portion of the indications to include the aforementioned deformity condition of adult degenerative scoliosis.